

It is submitted that the standard set forth is an incorrect one. Changes in molecular structure certainly impact antigenicity. Indeed, applicants showed that such changes improved antigenicity.

Assuming arguendo that a change in structure decreased immunogenicity - and there is no evidence of this - that does not mean the invention, as claimed would not function. The claimed invention relies on the ability of two molecules to bind to each other. The claimed invention does NOT require that the binding take place with a particular degree of strength, which is apparently what the Examiner would require. This, however, is not claimed.

It is also conceivable - but has not been shown by the Examiner - that there are molecules within the scope of the claims, which would not work; however, the enablement statute does not require that 100% of what is covered by the claims function. Rather, what the statute requires is a test of whether or not it would require undue experimentation to determine if a molecule does or does not work.

With respect to this, proper standard, it is a given that control, non-modified HCV peptides from the NS3 region do work. Hence, there is a basis for comparison. One can determine very easily if relevant antibodies are present in a sample by using a control HCV peptide, from the NS3 region. Assuming that binding takes place, then one simply tests the modified peptide in the same assay. How can this be said to constitute undue experimentation?

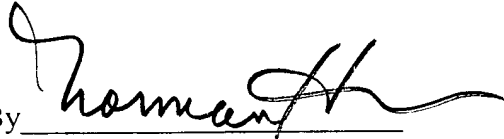
To argue his point, the Examiner cites non-prior art references, none of which deal with HCV, and certainly do not parallel the NS3 region of HCV. As has been established by the specification, the prosecution and the prior art, even within the HCV protein itself, what is true for one region is not necessarily true for others. Hence, the Examiner has used non-prior art references, describing different viruses, and unrelated proteins. The relevance of these materials must be questioned, and then dismissed.

With respect to the Examiner's dismissal of the declaration evidence, he has failed to rebut it. Unsupported conclusions by the Examiner cannot rebut what must be presumed correct, i.e., the declarant's data as well as her conclusions regarding it.

It is submitted that the Examiner has failed to make out a prima facie case, and withdrawal of the rejection is urged.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0624, under Order No. NY-HUBR 1067-US3-DIV from which the undersigned is authorized to draw.

Respectfully submitted,

By 

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Enclosures: Request for Extension of Time  
Check for Extension of Time